

SENT BY:

11- 9-94 : 4:48PM

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PRIVILEGED AND CONFIDENTIAL

SUBMISSION OF PHILIP MORRIS INCORPORATED
TO THE NATIONAL CANCER INSTITUTE
CONSENSUS CONFERENCE ON THE
FTC CIGARETTE TESTING METHODOLOGY
AND RATING SYSTEM

In response to Dr. Broder's letter of October 17, 1994, Philip Morris Incorporated ("Philip Morris") appreciates this opportunity to address the issues raised by the Chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, and the Chairman of the Federal Trade Commission, regarding the FTC's methodology for measuring the relative "tar" and nicotine yields of cigarette brands. We believe that the FTC method provides a well established basis for measuring and comparing the relative yields of cigarette brands under standardized conditions, and that the communication of FTC method yields to consumers for the last 25 years has provided them with objective information regarding the various cigarette brands available on the market, which they have used to make individual choices about the brands they wish to smoke.

We suggest that the Conference keep four points in mind:

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First, the FTC method was never intended to measure the "tar" or nicotine intake of any particular smoker. As the FTC explained in adopting the method:

"No two human smokers smoke in the same way. No individual smoker always smokes in the same fashion. . . .

. . . .

"The Cambridge Filter [FTC] Method does not and cannot measure these many variations in human smoking habits.

. . . Thus, the purpose of testing is not to determine the amount of tar and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by machine in accordance with the prescribed method.

. . .

"Accordingly, the testing method should not be considered defective because it does not rely on 'averages'. There are too many variables as to both smokers and smoking conditions for any average to be meaningful."

The FTC method was never intended to reflect all of the many behaviors and characteristics that define how a particular person smokes at any particular time, let alone the many physiological and metabolic variables that affect a person's blood chemistry. Indeed, the FTC method was designed to eliminate all of those variables to the greatest extent possible, and thereby focus not on the smoker, but on the product.

Second, the FTC method was developed through the cooperation of the scientific community, the tobacco

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industry, the Department of Agriculture, and the FTC. The common goal was to establish a fair, objective, and reproducible methodology for measuring product characteristics that are not easily measured. An unlit cigarette has no "tar"; nor does a cigarette burning statically. To create "tar," the cigarette must be smoked. And to assure objective and reproducible data, the cigarette must be smoked in a standardized manner, and there must be a standardized way of measuring the smoke created. This is no different from saying that to assure objective and reproducible mileage data, an automobile engine must be operated in a standardized manner and measured in a standardized way by the EPA.

Third, the use of the FTC method by both the Federal Trade Commission laboratory until 1987, and by the Tobacco Institute Testing Laboratory under the FTC's supervision both before and thereafter, has resulted in the publication of useful information that has assisted smokers in comparing brands. The "tar" and nicotine yield of a cigarette as measured by the FTC method typically correlates with a number of cigarette qualities that consumers find important, including taste, strength, mildness, and ease of draw. Cigarettes with the same or roughly the same "tar" and nicotine yields by FTC method are likely to be comparable in

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these respects, Cigarettes with meaningfully different "tar" and nicotine yields by FTC method will generally be distinguishable in these respects in ways that are predictable and well understood by consumers -- particularly with 25 years of experience with FTC method data. For a smoker who wants to switch to a milder brand, or to try a different brand with the same ease of draw, or the like, FTC method data provide meaningful and useful information.

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time*
Fourth, whether or not the FTC method ratings have any biological utility is a matter about which people may disagree, depending among other things upon their views on the basic smoking and health issues. To those non-smokers who believe that all cigarettes are equally bad and should be forbidden, ratings of relative yields may have no relevance. On the other hand, to those who choose to smoke, and even to critics of smoking who nonetheless believe that cigarette yields are significant in biologically pertinent respects, the FTC ratings of relative yields may provide information of interest. Different smokers -- and different researchers -- may have different views on these issues, and may utilize the FTC method ratings in different ways.

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A number of the FTC's questions to the Conference relate to "compensation," a term used to suggest that some smokers of lower yield cigarettes may sometimes alter their smoking behavior in ways that may tend to reduce the differences in yields among brands implied by their relative FTC method ratings. While there is a fair amount of recent literature on compensation, few studies have been performed that provide reliable data to establish the occurrence of this suggested phenomenon. The most rigorous of such studies suggest that if compensation occurs at all, it is typically limited in degree, and of short duration.¹ We discuss those studies in some detail below, and enclose copies for the Conference's review.

Philip Morris believes that because the FTC method has been and remains a validated and consistent system for providing information to consumers, it should be maintained. Smokers well understand that different people smoke cigarettes in different ways, that as individuals they smoke cigarettes differently at different times and in different situations, and that people may differ in any metabolic or physiological

See also

¹ Benowitz, N.L., Henningfield, J.E., "Establishing a Nicotine Threshold for Addiction: The Implications for Tobacco Regulation," The New England Journal of Medicine 331(2):123-25 (1994).

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response their bodies may have to tobacco smoke.

Nonetheless, smokers find FTC method ratings useful when comparing and selecting from competing brands.

While certain critics of cigarette smoking recently have asserted as dogma that FTC method ratings must be misleading, we are not aware of any reliable data suggesting that consumers are confused or misled into believing that the FTC method ratings represent the actual intake of "tar" and nicotine by each and every consumer from each and every cigarette. And it must be recalled that every cigarette pack and every cigarette advertisement carries a warning label written by Congress and declared by Congress to be an adequate warning. That should allay any possible concern over consumers being misled.

The Laboratory of the Government Chemist in the United Kingdom ("LGC"), while noting that some studies had suggested the presence of some compensation, concluded that for several reasons the "tar" and nicotine testing system was useful and should be retained:

"Firstly, some evidence is conflicting, for example Rawbone has reported results indicating that human and machine yields may be reasonably close. Secondly, Government legislation and health policy towards smoking in many countries is based on a system of classifying cigarettes based on

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existing methodology. This system is likely to continue until overtaken by any new system evolved. Thirdly, compensation is restricted to established smokers. For those with little experience of the practice ranked tables will still be relevant and are therefore useful in promoting health policies, particularly to the young."²

The results of 25 years of publication of FTC method ratings have been twofold:

1. A broad array of cigarette brands has emerged at virtually every point on the FTC method spectrum. Consumers have been given a broad range of cigarettes, with different "tar" and nicotine yields, from which to choose.

2. The average FTC method yields of cigarettes have declined significantly since FTC method testing, and the publication of FTC method ratings, began. Yet, contrary to what a compensation hypothesis would suggest, the per capita cigarette consumption in the United States has not increased.

Unless one believes that compensation is so complete that it never makes any difference for any smoker which brand he or she smokes -- and we are not aware of any real support for such an extremist

² Darrall, K.G., "Smoking Machine Parameters and Cigarette Smoke Yields," The Science of the Total Environment 74:263-78 (1988).

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position -- then these results would suggest that the publication of FTC ratings has led to an overall decrease in the "tar" and nicotine intake of smokers. In light of this trend, we would strongly question whether even those who believe smoking to be an undesirable activity would want to abandon or substantially alter a testing methodology which appears to have contributed to modifications in smoking behavior of the sort that public health authorities have encouraged.

The Conference might conclude that it would be desirable to define the manner in which the "average" smoker smokes different types of cigarettes, at different times and under different circumstances. Doing so might be explored through surveys of smokers, each of whom would have to make ~~estimates~~ about his or her "normal" pattern of smoking, or, more rigorously, through biological testing of fluid or tissue samples obtained from multitudes of smokers. To date, reliable data along these lines have not been generated, and the Conference might recommend suitable approaches for further research, while keeping in mind that individual and situational differences are unavoidable.

But such behavioral and individual characteristics should not be used to distort the FTC

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testing method or to question its utility. No smoker can ever be certain whether his or her behavior -- or his or her metabolism -- is "average," or to what degree it differs from "average." Philip Morris believes that an overlay of subjective behavioral or physiological variables on the objective criteria of the FTC method would lead only to less comparable ratings and greater potential for consumer confusion.

Moreover, changing the parameters employed in the FTC method would not change the relative ratings of brands (although it probably would create confusion as to comparability with existing data and with methodologies in use in other parts of the world). Studies by the Laboratory of the Government Chemist, commissioned by the Independent Scientific Committee on Smoking and Health and financed by the Department of Health and Social Security in the United Kingdom,³ demonstrate that the relative ratings of "tar" and nicotine yield from different brands do not change in any substantial way even if the standard smoking machine parameters are altered within realistic limits.

The conclusion of the LGC study was that "altering smoking machine parameters does not

³ Darrall, K.G., "Smoking Machine Parameters and Cigarette Smoke Yields," The Science of the Total Environment 74:263-78 (1988).

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substantially alter the ranking positions of brands as currently published." The LGC study also concluded that "it seems unlikely that changing the present standard smoking parameters would provide substantially more relevant or accurate information to the smoker."

Some researchers have suggested that the FTC method should be replaced with an assay of the nicotine (and perhaps other constituent materials) in the tobacco in the unlit cigarette rod (so-called "rod content"). For an obvious reason -- ~~consumers~~ ^{smokers} do not eat their cigarettes -- such an approach would result in misleading information, because it does not take account of filtration, dilution, tobacco density, and the many other factors that, along with rod content, affect "tar" and nicotine yields.

Authors may disagree about the precise extent of the effects of filtration or dilution in different contexts and for different consumers, but there is, to our knowledge, no debate that filtration and dilution -- particularly using current technology -- dramatically reduce the yield of all smoke constituents. Yet were the FTC method to be replaced by an assay of rod content, it is possible that cigarettes designed and widely acknowledged to yield lower "tar" and nicotine would be rated comparably with the unfiltered, undiluted

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cigarettes that many public health and consumer organizations have encouraged smokers to avoid. If cigarettes were rated by so-called rod content, undeniable differences in yields would be masked from consumers, and smokers might become more inclined to switch to the brands with high FTC method yields.

We note that countries around the world, including all government operated testing laboratories in the European Union, are moving to a uniform testing methodology based on the FTC method and endorsed by the International Organization for Standardization ("ISO")⁴. If there were to be any change in the FTC method, the most reasonable change would be the adoption of the strict ISO method. The ISO method is largely identical to the existing FTC method, and the yields measured are comparable. However, the ISO documents are more detailed and specific in a number of respects, which contributes to uniformity among testing laboratories around the world.

⁴ ISO 3308 ("Routine analytical cigarette-smoking machine -- Definitions and standard conditions"); ISO 4387 ("Cigarettes -- Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine"), International Organization for Standardization (1991).

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1. The FTC Method Was Adopted To Provide an Objective and Reproducible Methodology for Measuring the Relative Yields of Cigarette Brands Under Standard Conditions

While "tar" has long been considered a significant characteristic of cigarettes, it is not a well defined term. Colloquially, the term has for decades been employed to describe some or all of the particulate phase organic compounds present in tobacco smoke. Those compounds, which comprise both combustion products and pyrolysis products produced at or near the burning end of the cigarette, may or may not be present at all in the tobacco of an unlit cigarette or in the smoke emanating from the lit end of a statically burning cigarette. And the extent to which those compounds are created depends largely on the air flow through the cigarette, as well as on atmospheric factors such as temperature and humidity. In other words, an unlit cigarette has no measurable "tar"; to create measurable "tar," the cigarette must be smoked; and the manner and conditions in which the cigarette is smoked will determine how much, if any, "tar" is created.

By contrast, nicotine is a well defined and measurable compound present in the tobacco rod. The amount of nicotine in tobacco smoke, however, like the amount of "tar," depends on smoking conditions.

Nicotine is subject both to capture by the filter fibers

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and to condensation in the filter, depending on flow rates. And a statically burning cigarette will typically produce nicotine in the vapor phase, rather than as a particulate.

Accordingly, to give consumers useful information regarding the relative characteristics of cigarette brands, it was necessary to define "tar," and specifically to create a standard methodology for creating and then measuring "tar" and nicotine yields. By notice of August 1, 1967, the FTC adopted a standard definition of "tar" and nicotine, and a standard methodology for measuring the "tar" and nicotine yields of cigarettes:

"1. Smoke cigarettes to a 23 mm. butt length, or to the length of the filter and overwrap plus 3 mm. if in excess of 23 mm.,

"2. Base results on a test of 100 cigarettes per brand, or type,

"3. Cigarettes to be tested will be selected on a random basis, as opposed to 'weight selection',

"4. Determine particulate matter on a 'dry' basis employing the gas chromatography method published by C. H. Sloan and B.J. Sublett in Tobacco Science 9, page 70, 1965, as modified by F.J. Schultz' and A.W. Spears' report published in Tobacco Vol. 162, No. 24, page 32, dated June 17, 1966, to determine the moisture content,

"5. Determine and report the 'tar' content after subtracting moisture and

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alkaloids as nicotine) from particulate matter,

"6. Report tar content to the nearest whole milligram and nicotine content to the nearest 1/10 milligrams."⁵

In adopting this methodology, the Commission made clear in its "Statement of Considerations" that it was not attempting "to gauge the test to the amount of smoke, or tar and nicotine, which the 'average' smoker will draw from any particular cigarette." The Commission went on to explain the infeasibility and inappropriateness of attempting to adopt a methodology designed to predict the intake of any particular human smoker:

"No two human smokers smoke in the same way. No individual smoker always smokes in the same fashion. The speed at which one smokes varies both among smokers, and usually also varies with the same individual under different circumstances even within the same day. Some take long puffs (or draws); some take short puffs. That variation affects the tar and nicotine quantity in the smoke generated.

"Even with the same type of cigarette, individual smokers take a different number of puffs per cigarette depending upon the circumstances. When concentrating, or talking, the number of puffs is usually less. When listening, or required to listen to another person talking, the number of puffs per cigarette, as well as the

⁵ 32 Fed. Reg. 11178 (Aug. 1, 1967).

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duration of each puff, usually increases. Smoking rates while reading a book may differ from smoking rates while viewing a television program. The number of puffs and puff duration (as well as butt length) will vary according to emotional state. Some smokers customarily put their cigarettes down in an ashtray where they burn between puffs; other smokers constantly hold cigarettes in their mouths; others hold them between their fingers.

"The Cambridge Filter Method does not and cannot measure these many variations in human smoking habits. It does not measure tar or nicotine in the smoke generated while the cigarette is not being puffed. It does not measure all of the tar and nicotine in any cigarette, but only that in the smoke drawn in the standardized machine smoking according to the prescribed method. Thus, the purpose of testing is not to determine the amount of tar and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by machine in accordance with the prescribed method.

"Accordingly, the testing method should not be considered defective because it does not rely on 'averages'. There are too many variables as to both smokers and smoking conditions for any average to be meaningful. Test results phased in terms of an 'average' smoker could be misleading to the public, because a smoker has no way of knowing how closely his smoking habits conform to those of the purportedly 'average' smoker. It should be emphasized that the Cambridge Filter Method itself did not purport to duplicate an 'average' smoker. Rather, it was an amalgam of many choices -- some of them arbitrary. For example, the temperature and

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humidity specified in that Method were not determined by reference to the 'average' temperature or the 'average' humidity at which people smoke cigarettes. There is no human smoker who smokes, and no cigarette that is smoked, under conditions that precisely duplicate either the Cambridge Filter Method in its original form or as modified by the Commission. Thus, to reiterate, the uniform method determined by the Commission has as its purpose measurement of the tar and nicotine generated by cigarettes when smoked according to that procedure."
(Emphasis supplied.)⁶

The FTC established a laboratory, and once or twice a year issued reports on the "tar" and nicotine yields of every significant cigarette brand on the market.

Over the years, questions have arisen from time to time regarding modification of the FTC method, and the Commission has dealt with them in a sensible manner that furthered the goal of standardized product testing. The most serious such questions arose in 1981, when the Commission became aware of a new cigarette brand, Barclay, which employed a unique "bypass" filter. The filter operated in such a way that the cigarettes were highly diluted when machine smoked according to the FTC

⁶ While the adoption of the FTC method by the Commission was unanimous, Chairman Dixon did dissent on one point. He expressed the belief that smoking cigarettes on the machine to a 23 millimeter butt length was unrealistic because the available evidence suggested that few smokers smoke that much of a cigarette, and therefore a 23 millimeter butt length would tend to overstate "tar" and nicotine yields.

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method, but comparatively undiluted when smoked by a human smoker. The history of the subsequent investigation and litigation is enlightening in its vindication of the FTC method against an attack, by a tobacco company, that the FTC method was worthless and misleading.

As noted above, one of the principal mechanisms by which cigarettes differ in "tar" and nicotine yield is dilution -- the inclusion of ventilation perforations around the circumference of the filter to permit air from around the filter to be drawn in and mixed with smoke drawn through the tobacco rod. Unlike other cigarette filters, the Barclay filter permitted dilution only through nonporous peripheral channels which were necessarily blocked by a human smoker's lips -- limiting dilution -- but were open in the smoking machine. The FTC concluded that while machine smoking of Barclay cigarettes by FTC method indicated a "tar" yield below 1 mg, Barclay was actually comparable to brands that measured 3 to 7 mg "tar" by FTC method.

The principal defense of the manufacturer was the same as the basis of many of today's criticisms of the FTC method. In litigation instituted by the FTC, the manufacturer contended that "recent scientific evidence demonstrates that the FTC system is so flawed that it is

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itself deceptive." FTC v. Brown & Williamson Tobacco Corp., 580 F. Supp. 981, 984 (D.D.C. 1983), aff'd, 778 F.2d 35 (D.C. Cir. 1984). In particular, the manufacturer contended that analysis of cotinine in the blood of smokers established the absence of any correlation between the FTC method rating of cigarette brands and the amount of smoke actually received by smokers of those brands.

Following extensive consultation with three outside technical experts -- Dr. Lynn Kozlowski, then of the University of Toronto; Dr. Michael Guerin of the Oak Ridge National Laboratory; and Dr. Fred Bock, then of the Papanicolaou Cancer Research Center -- and informal consultation with other experts -- including Dr. Neal Benowitz of the University of California -- the Commission brought an action in federal district court and obtained an injunction against the continued advertising of Barclay as a 1 mg cigarette.⁷ In granting the injunction sought by the FTC, Judge Gerhard Gesell rejected the Barclay manufacturer's attack upon

⁷ Judith Wilkenfeld, Esq., the Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection, of the FTC identified as the FTC contact in Chairman Steiger's letter to the Conference, and now reportedly on detail to the Office of Policy in the Office of the Commissioner of Food and Drugs, served ably as one of the Commission's trial counsel in the Barclay litigation.

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the FTC method ratings, and agreed with the Commission that the FTC method was valid and useful:

"The FTC rating system has enjoyed almost universal acceptance for over a decade. Recently, however, the system has been subjected to criticism, largely but not entirely in connection with the Barclay controversy. Seeking to defeat the present suit by demonstrating that the entire FTC rating system is itself misleading, B & W has presented to the Court several 'cotinine' studies. Such studies measure by indirect means the amount of nicotine a smoker actually ingests. The principal studies upon which B & W relies are an '800-person' study conducted by Dr. Gio Gori, a B & W consultant, and a study by Dr. Neal Benowitz.

"

"This evidence, however, is not sufficient to lead the Court to hold that the FTC system is meaningless or deceptive. First, the Gori study does in fact validate the FTC system at least to a certain extent by demonstrating that a positive relationship exists between nominal FTC ratings and blood levels of nicotine. Even if the levels of tar and nicotine differ by only 30-40%, this difference has significant health implications, as Dr. Gori acknowledged in his testimony. Exactly how small a difference is of significance is impossible to determine given the current state of scientific knowledge, and it is possible that even very small differences might account for a significant number of early deaths across the nation. Furthermore, because the relatively small difference in nicotine levels between the high and low FTC-rated cigarettes is due in part to the manner in which they are smoked -- the 'compensation' effect --

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a smoker who avoids engaging in compensatory behavior would still receive tar and nicotine into his mouth in rough proportion to the FTC numbers. Even accepting Dr. Gori's results, his study thus fails to discredit the FTC system.

"A second reason exists for finding that B & W has failed to demonstrate that the FTC system is not of value to consumers. The FTC system attempts only to determine how much relative tar and nicotine a smoker would get in his mouth were he to smoke two cigarettes in the same manner. B & W has utterly failed to show that the system does not do this. Nor has it shown that a better method for determining the relative health hazards of the many different varieties of cigarettes on the market is currently feasible. Dr. Gori, while arguing for the use of cotinine studies rather than the current rating system, estimated it would take a study using 40,000 people to test properly the brands of cigarettes now rated by the FTC. Moreover, even such a massive and expensive study would leave unanswered questions. The cotinine method measures only the amount of nicotine a smoker ingests. The major health danger to smokers comes not from the ingestion of nicotine, however, but from the ingestion and retention of tar in the body. Because actual tar ingestion cannot be directly measured by any known process, in order to derive tar data from the cotinine experiments it is necessary to calculate a 'tar/nicotine' ratio for each brand based on independent experiments. How this ratio can properly be determined is the subject of scientific dispute, and the issue has yet to be resolved." 580 F. Supp. at 984-86 (emphasis supplied) (footnotes omitted).

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2. The FTC Method Ratings Have Provided Useful Comparative Information to Consumers

For two and one-half decades, the FTC method "tar" and nicotine ratings have been employed to provide information to consumers. One reason is that the FTC method produces numerical results with no intuitive absolute meaning, somewhat akin to grams-per-serving nutritional information. Probably few smokers know exactly how "tar" or nicotine is measured, exactly how much one milligram is, or exactly how the smoking machine operates. Standing alone, the statement that a cigarette brand delivers 5 mg "tar" by FTC method may mean as little or as much as the statement that a particular automobile has a 120 horsepower engine. In the context of a system of comparative ratings, however, particularly when the system has been in place for many years, such statements convey a great deal of information. The statement that a brand yields 5 mg "tar" tells a smoker what he or she wants to know -- that that cigarette brand will have mildness, ease of draw, and other characteristics comparable to those of other 5 mg (or 4 mg or 6 mg) brands that the smoker has tried, and notably different from those of 10 mg brands and 1 mg brands that the smoker has tried.

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Smokers also understand that, if smoked the same way, a 5 mg brand will have a smoke yield like that of other 5 mg brands the smoker has tried, lower than that of 10 mg brands the smoker has tried, and higher than that of 1 mg brands the smoker has tried. As the court noted in the Barclay case:

"Since to a consumer a milligram tar rating has no significance except in relation to other such ratings, a rating number standing alone or based on a different rating scale gives no useful information about relative health risk. It can only be understood in reference to ratings found in other cigarette advertisements, which are FTC ratings." 580 F. Supp. at 987 (footnote omitted).

Individual smokers understand that their actual "tar" and nicotine intake depends on a number of factors, including the number of cigarettes smoked, the number of puffs taken on each cigarette, and the extent to which the smoke is inhaled. FTC "tar" and nicotine ratings do not tell and are not intended to tell individual consumers anything about those factors. But given the inherent variability of those factors -- both among consumers, and for an individual consumer at different times and in different circumstances -- it is difficult to posit a workable alternative to the FTC method that would be more useful and informative.

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As noted above, the effect of 25 years of FTC testing has been the proliferation of brands at every point on the FTC method "tar" and nicotine spectrum. Many smokers have chosen to switch to lower yield cigarettes, and over the years, the average yield of cigarettes generally has declined markedly.

On a worldwide basis, including the domestic cigarette market:

- Sales weighted average "tar" and nicotine cigarette yields have steadily declined;
- Per capita cigarette consumption has ~~increased~~ declined;
- Sales in the full-flavored segment (>15 mg "tar") have continually declined while sales in the light and ultra light segments (<8 mg "tar") have continually increased;
- The average number of cigarettes smoked per smoker per day has remained relatively constant.

During the period 1974-93, the annual domestic market share of cigarettes of greater than 1.2 mg nicotine yield declined some 1.7% per year, while cigarettes with nicotine yield equal to or less than 0.8 mg increased correspondingly. All of these facts point to smokers making a choice to move to lower "tar" and nicotine cigarettes.

Reflecting on the utility of the FTC method ratings, Chairman Daniel Oliver of the FTC testified at a House Subcommittee hearing in 1988:

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"As a general matter I believe that advertisements that accurately convey information on 'tar' and nicotine content can be a valuable source of information to consumers. Advertising that provides comparative information on different 'tar' and nicotine levels can be especially useful."

3. **Suggestions of "Compensation"**
Do Not Eliminate the Utility
of the FTC Method Ratings

The FTC method for measuring the "tar" and nicotine yields of cigarettes provides comparative information about cigarette characteristics. It has never been suggested that an individual smoker's "tar" or nicotine intake was determined solely by FTC method yields. A host of individual factors would be involved, including:

- The number of cigarettes smoked;
- The number of puffs taken per cigarette;
- The volume of each puff;
- The duration of each puff;
- The depth of smoke inhalation;
- The dilution of smoke with air prior to inhalation;
- The smoker's unique physiology and metabolism.

The term "compensation" has been variously applied to any or all of the situations in which these

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and other variables may affect a particular smoker's intake of "tar" and nicotine. The prevalence and extent of compensation is a matter of debate, but we believe that there are at least three points upon which observers agree:

First, it is difficult to derive precise data regarding compensation, and to date very few reliable data exist. There are no reliable techniques for directly measuring the "tar" and nicotine intake of a particular smoker, and indirect measurements are imprecise and subject to error.

For a variety of reasons, the most commonly employed indicator of an individual's inhalation of nicotine has become the level of cotinine, an indirect metabolite of nicotine, in his or her blood. The metabolism of nicotine is complex, however, and the blood cotinine levels of different persons exposed to the same amount of nicotine may vary substantially. It is also not clear if there is any readily quantifiable relationship between blood levels of cotinine and a smoker's intake of "tar."

Second, the larger and more carefully conducted studies have found little if any significant compensation. And to the extent that any studies have found indications of compensation, that compensation has

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been limited in extent and temporary in duration. We are not aware of any competent study that has ever found that large numbers of smokers compensated completely and for extended periods of time when switching to cigarettes of lower FTC method yield.

Third, there is little if anything in the literature that would enable anyone to draw quantitative conclusions about the experiences of large numbers of people sufficient to permit any sort of "adjustment" of FTC method measurements, even if such adjustment were considered desirable. Moreover, any adjustment for compensation would not account for the large differences among smokers -- and, indeed, differences in the way a single smoker smoked at different times. Any such adjustment would therefore be of at most limited validity, and potentially misleading.

The available research indicates that to the extent there may be compensation, mechanisms vary greatly from individual to individual. Early research, conducted with cigarettes manufactured with technology far different from that employed today, indicated that some smokers partially blocked some of the filter perforations designed to increase ventilation, although it was never established whether this was deliberate or inadvertent, and the exact consequences of such blockage

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remain unclear. But there is no indication that such blocking has continued in recent years, since the advent of more sophisticated technologies, such as laser perforation of filters and papers.

Other reported compensation mechanisms include -- again in the short-term -- the smoking of some additional cigarettes, increased puff count, and, in some cases, greater puff volume. However, these very same phenomena also have been associated with everyday situations totally unrelated to "tar" and nicotine levels in cigarettes, such as time of day, test subject stress level, environment in which the cigarette is smoked, anticipation of future availability, and so forth. It appears that no research designed to analyze compensation in the context of shifts from higher to lower FTC method yield cigarettes has even attempted to account adequately for the confounding role these commonly present factors can play. Some research -- by misunderstanding if not by design -- has exacerbated the effects of some of these confounding factors.

a. "Tar" and Nicotine Intake Decrease in a Linear Pattern When People Smoke Cigarettes with Lower FTC Method Yields

It is difficult to derive reliable data comparing actual "tar" and nicotine intake by smokers with FTC

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method yields. Nevertheless, the most carefully conducted studies to date have tended to find direct and linear relationships between actual intake and FTC method yield. Even those researchers who report finding some compensation conclude that smokers consume lower quantities of "tar" and nicotine when they smoke cigarettes with lower FTC method yields.⁸ According to Dr. M.A.H. Russell, for example, despite some smokers' apparent compensatory behavior, "their intake of the three major smoke components [is] still lower to a statistically and clinically significant degree."⁹

Zacny and Stitzer (1988)¹⁰ conducted a brand-switching study to compare the cotinine levels of smokers using high, medium, low, and ultra low FTC method yield cigarettes. The plasma cotinine levels of the ultra low cigarette smokers were significantly lower

⁸ See U.S. Department of Health and Human Services, The Health Consequences of Smoking: Nicotine Addiction: a report of the Surgeon General 162 (1988) (concluding that "brand switching may result in somewhat decreased levels of intake of nicotine and other constituents of tobacco smoke").

⁹ Russell, M.A.H., Jarvis, M.J., Feyerabend, C., Salcojee, Y., "Reduction of tar, nicotine and carbon monoxide intake in low tar smokers," Journal of Epidemiology and Community Health 40:80-85 (1986).

¹⁰ Zacny, J., Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," Journal of Pharmacology and Experimental Therapeutics 246(2):619-27 (1988).

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than those of the medium yield cigarette smokers, and the plasma cotinine levels of the low yield cigarette smokers were significantly lower than those of the high yield cigarette smokers. While the authors thought that there had been some compensation, they concluded that "nicotine, cotinine and CO exposure levels from commercial brand cigarettes are related in an orderly manner to cigarette yield." Even smokers who may appear partially to compensate while smoking lower yield cigarettes still have a significantly lower intake of "tar" and nicotine.¹¹

Although some authors have stated that smokers compensate fully when smoking lower yield cigarettes, the data in the studies do not support such a conclusion.¹² Rather smokers compensate at most only

¹¹ Stephen, A., Frost, C., Thompson, S., Wald, N., "Estimating the extent of compensatory smoking," in Wald, N., Froggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 101-15 (1989) ("The studies are . . . consistent in demonstrating that compensation is not complete. Low tar cigarette smokers inhale less CO and nicotine than high tar cigarette smokers.").

¹² See Russell, M.A.H., Jarvis, M.J., Feyerabend, C., Saloojee, Y., "Reduction of tar, nicotine and carbon monoxide intake in low tar smokers," Journal of Epidemiology and Community Health 40:80-85 (1986) (disagreeing with other authors' conclusions of complete compensation because results showed a reduction in nicotine intake).

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partially.¹³ Studies show that there is a linear correlation between higher cigarette yields by FTC method and higher cotinine levels.

For example, in studying the plasma cotinine levels of 125 smokers, Rosa *et al.* (1992) discovered that the cotinine levels of smokers decreased proportionally to the FTC method yield of nicotine in the cigarettes smoked.¹⁴ The authors concluded that smokers did not compensate for middle to higher yields, and compensated at most partially in smoking ultra low yield brands.

In a Bridges *et al.* (1990) study of 170 male smokers smoking their regular brand of cigarettes, the authors discovered that plasma nicotine and cotinine concentrations "appeared to increase progressively with

¹³ See, e.g., Russell, M.A.H., Sutton, S.R., Iyer, R., Feyerband, C., Vesey, C.J., "Long-Term Switching to Low-Tar Low-Nicotine Cigarettes," British Journal of Addiction 77:145-58 (1982).

Bridges, R., Humble, J., Turbek, J., Rehm, S., "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," Eur. J. Respir. Dis. 69 (Suppl. 146):129-37 (1986).

¹⁴ Rosa, M., Pacifici, R., Altieri, I., Pichini, S., Ottaviani, G., Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," Clinical Pharmacology Ther 52(3):324-29 (1992).

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increasing nicotine yield of the cigarette.¹⁵ They stated that these increases were supported "by the linear relationships between plasma nicotine or cotinine concentrations and the cigarette yield in smokers consuming filter cigarettes." The results of another study by Bridges *et al.* (1986) showed that the FTC method nicotine yields of cigarettes correlated significantly with plasma cotinine levels in smokers, showing a linear relationship between the FTC method yield and the plasma cotinine measurements.¹⁶ The authors concluded that "if tobacco related obstructive pulmonary diseases are associated with increased smoke exposure, a lesser degree of lung injury may be expected in smokers using low-yield cigarettes." (Emphasis supplied.)

To be of any use at all in assessing compensation, studies must have an adequate number of subjects to encompass the individual variations in smoking behavior and metabolism, and must be of

¹⁵ Bridges, R., Combs, J., Humble, J., Turbak, J., Rehm, S., Haley, N., "Population Characteristics and Cigarette Yields as Determinants of Smoke Exposure," Pharmacology, Biochemistry & Behavior 37(1):17-28 (1990).

¹⁶ Bridges, R., Humble, J., Turbak, J., Rehm, S., "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," Eur. J. Respir. Dis. 69 (Suppl. 146):129-37 (1986).

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sufficient duration to be meaningful. Insufficient duration has been a major defect in some experimentation. For 34 studies using indirect evidence regarding nicotine "regulation," the average trial length was 11 days, with a minimum of 20 minutes of observation and a maximum of 12 weeks. An additional issue is that the number of subjects averaged only 32, with a minimum of 3 and a maximum of 330.¹⁷

One of the more reasonably conducted studies was that of Russell *et al.*¹⁸ Based on their research that used multi-week time studies of smokers who switched to lower yield cigarettes, the authors concluded that "[c]igarette consumption was not significantly changed and there was no evidence of any compensatory increase in nicotine intake at mouth level for the cigarettes smoked outside the laboratory." They further concluded that both plasma nicotine and cotinine were reduced by an identical 30% after the switch.

Byrd *et al.*¹⁹ investigated the inter-individual

¹⁷ See e.g., Russell, M.A.H., Sutton, S.R., Iyer, R., Feyerabend, C., and Vesey, C.J., "Long-Term Switching to Low-Tar Low-Nicotine Cigarettes," British Journal of Addiction 77:145-58 (1982).

¹⁸ *Id.*

¹⁹ Byrd, G., Robinson, J., Caldwell, W., deBethizy, D., "Inter-Individual Variation of Nicotine Uptake Among Smokers," Paper P127, International Symposium on
[Footnote continued on next page]

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variation of nicotine intake of 33 smokers who smoked ad libitum their usual brand of cigarette. Nicotine and its metabolites, including the glucuronide conjugates, were determined in 24 hour urine samples for smokers of brands with FTC method nicotine yields of 0.14, 0.49, 0.67 and 1.13 mg/cigarette. The increase in average nicotine intake, without regard to the number of cigarettes smoked, was linear with increasing cigarette yield by FTC method. Although variations among individual smokers were significant, the linear relationship of the mean intake with the FTC method yield suggests that the FTC value predicts actual nicotine intake. Smokers of low yield cigarettes did not appear to ingest more nicotine than proportionate to the FTC value.

A similar result was obtained by plotting nicotine intake per cigarette smoked as a function of yield by FTC method.²⁰ When the mass balance of nicotine was made by accounting for 24 hour urine volume, and the metabolic differences between subjects was assessed by determining the nicotine metabolites as

[Footnote continued from previous page]
Nicotine: The Effects of Nicotine on Biological Systems
II, Montreal, July 1994.

²⁰ Id.

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well as the nicotine, the correlation between the FTC method yield and the intake per cigarette was excellent.

A British paper in 1984 attempted to investigate compensation not by measuring biological markers of smokers, but by determining the amount of nicotine drawn through spent cigarette butts. This methodology minimized the impact of metabolic variability, and permitted analysis of cigarettes smoked freely by some 260 smokers under non-laboratory conditions. The author concluded that:

"[o]verall the results obtained from this study are consistent with the published government tar league tables in showing that for a middle tar cigarette most (98%) smokers achieve a delivery within or below the middle tar band of 16.50-22.49 mg, while among low tar smokers about 70% take 10.49 mg or less from their product. Although somewhat arbitrary in terms of the butt length and puff characteristics used, standard smoking machine tar yields appear to reflect average human mouth intake as estimated in the present study."²¹

b. Compensation Is at Most
a Short-Term Phenomenon

Very few studies have been conducted to determine the effect of switching to a lower yield cigarette for

²¹ Rawbone, R.G., "Switching to low tar cigarettes: are the tar league tables relevant?", *Thorax* 39:657-62 (1984).

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an extended period of time. Some smokers may take time to become acclimated to lower yield cigarettes.²² Drs. Neal Benowitz and Jack Henningfield have indicated that compensation appears to be temporary. In the July 14, 1994 issue of The New England Journal of Medicine, Drs. Benowitz and Henningfield stated that what they characterized as "[o]vercompensation . . . appears, however to persist only for days or weeks. In long-term studies of carbon monoxide exposure after subjects switched to low-yield cigarettes, compensatory oversmoking appears not to persist."²³

c. Low "Tar" Cigarette Smokers
Do Not Smoke More Cigarettes

In addition, researchers almost unanimously agree that smokers of low FTC method yield brands do not smoke higher numbers of cigarettes. For example, Hofer, Nil and Battig (1991) concluded from a cross-sectional study

²² See Rosa, M., Pacifici, R., Altieri, I., Pichini, S., Ottaviani, G., Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," Clinical Pharmacology Ther 52(3):324-29 (1992) ("It is necessary to consider that several studies never take into consideration the time of accommodation to fit a new level of nicotine." (footnotes omitted)).

²³ Benowitz, N.L., Henningfield, J.E., "Establishing a Nicotine Threshold for Addiction: The Implications for Tobacco Regulation," The New England Journal of Medicine 331(2):123-25 (1994).

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of 140 smokers that "[t]he daily consumption of cigarettes shows no increasing trend for lower yield cigarettes, and this appears from the present results as well as from those reported in the literature."²⁴ Many other studies have come to the same conclusion.²⁵

d. Experiments Purporting to Find Compensation Are of Doubtful Reliability

As noted above, a number of studies have confirmed the utility of FTC method data as predictors of actual smoker intake of "tar" and nicotine, even though the FTC method was not designed for that purpose. Nevertheless, some authors have inferred that smokers

²⁴ Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology Biochemistry & Behavior 40:139-49 (1991).

²⁵ Rosa, M., Pacifici, R., Altieri, I., Pichini, S., Ottaviani, G., Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," Clinical Pharmacology Ther 52(3):324-29 (1992).

Bridges, R., Combs, J., Humble, J., Turbek, J., Rahm, S., Haley, N., "Population Characteristics and Cigarette Yield as Determinants of Smoke Exposure," Pharmacology, Biochemistry & Behavior 37(1):17-28 (1990).

Armitage, A.K., Alexander, J., Hopkins, R., Ward, C., "Evaluation of a low to middle tar/medium nicotine cigarette designed to maintain nicotine delivery to the smoker," Psychopharmacology 96:447-53 (1988).

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may alter their puffing behavior to increase the smoke obtained from low FTC method yield cigarettes.²⁶

Some studies have suggested that some smokers puff more rapidly and take larger puffs from lower yield cigarettes.²⁷ Some of the same studies have suggested, however, that smokers take fewer puffs from lower yield cigarettes,²⁸ an opposite effect. Although some smokers in one study did appear to alter puffing behavior according to the yield of their cigarette brand, they exhibited partial compensation only and did not smoke low-yield cigarettes in a manner that made them

²⁶ See Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology Biochemistry & Behavior 40:139-49 (1991) ("the compensational effect with low yield cigarettes is mainly due to increased puff volume").

Bridges, R., Combs, J., Humble, J., Turbek, J., Rehm, S., Haley, N., "Population Characteristics and Cigarette Yield as Determinants of Smoke Exposure," Pharmacology, Biochemistry & Behavior 37(1):17-28 (1990).

²⁷ Zacny, J., Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," Journal of Pharmacology and Experimental Therapeutics 246(2):619-27 (1988).

Bridges, R., Humble, J., Turbek, J., Rehm, S., "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," Eur. J. Respir. Dis. 69 (Suppl. 146):129-37 (1986).

²⁸ Zacny, J., Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," Journal of Pharmacology and Experimental Therapeutics 246(2):619-27 (1988).

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equivalent to cigarettes with higher FTC method yields.²⁹

Apart from the internally inconsistent results of some of these studies, many of them have used questionable methods. For example, in one study³⁰ -- the title of which ("Puff volume increases when low-nicotine cigarettes are smoked") apparently was intended to suggest that experimental data had established one variety of compensation as prevalent -- the cigarettes were described by the authors as having high, medium, and low nicotine yields, but as being alike in other respects. However, a review of the methodology employed reveals that during conduct of the study, the subjects were forced to abstain from smoking for 8-10 hours, then given a cigarette under cumbersome test conditions including puff flow measurement equipment. The cigarettes were "University of Kentucky alkaloid research cigarettes," unflavored, unfiltered, and admittedly dry, and satisfaction was rated as minimal.

²⁹ See Bridges, R., Humble, J., Turbek, J., Rehm, S., "Smoking History, Cigarette Yield and Smoking Behavior as Determinants of Smoke Exposure," Eur. J. Respir. Dis. 69 (Suppl. 146):129-37 (1986).

³⁰ Herning, R., Jones, R., Bachman, J., Mines, A., "Puff volume increases when low-nicotine cigarettes are smoked," British Medical Journal 283:187-89 (1981).

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The initial puff volumes were measured for all test cigarettes as larger for the first two puffs, less for the middle two, and approximately 35 ml (the same puff volume used in the FTC method) or less for the last two puffs. Moreover, the authors found no increase in the number of puffs taken on the low nicotine yield cigarettes, and concluded that smokers did not increase puff volume sufficiently to extract as much nicotine from the low nicotine cigarettes as from the higher nicotine cigarettes.

Accordingly, not only is the title of the study somewhat misleading, but its data are suspect. The puff volumes for the low nicotine cigarettes declined rapidly with successive puffs, and the study established only what everyone already knows: that it is not uncommon, after abstinence, to pursue with vigor any activity that one expects to find pleasurable. From this type of response to an unusual situation, however, one cannot leap to conclusions about regular behavior.

The extent to which smokers block filter dilution perforations is another point of disagreement among authors. In a study conducted by Zacny and Stitzer (1988),³¹ the authors stated that out of 1,631 cigarette

³¹ Zacny, J., Stitzer, M., "Cigarette Brand-Switching: Effects on Smoke Exposure and Smoking Behavior," [Footnote continued on next page]

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butts examined, only 0.1 percent had completely blocked ventilation holes, 72 percent were unblocked, and 6 percent had partially blocked holes. 22 percent of the filters were difficult to classify as either blocked or partially blocked. Zacny and Stitzer concluded that the study "provided little evidence for consistent filter vent-blocking when subjects smoked ultra low-yield cigarettes," even though one would expect to encounter the greatest likelihood of compensation with such cigarettes.

Based only on a set of interviews of office workers who had switched to lower-yield cigarettes, a 1982 paper stated that 52% of the smokers "self-reported hole-blocking" when they first began smoking these cigarettes.³² Of these, 39% reported blocking the holes with their fingers, 20% with their lips and 20% by the use of tape, a rather bizarre behavior. The experimental evidence of ventilation hole blockage was a visual inspection of the "tar" stain on spent filters of cigarettes smoked during the interviews. Some of this

[Footnote continued from previous page]
Journal of Pharmacology and Experimental Therapeutics
246(2):619-27 (1988).

³² Kozlowski, L., Rickert, W., Pope, M., Robinson, J., Frecker, R., "Estimating the Yield to Smokers of Tar, Nicotine and Carbon Monoxide from the 'Lowest Yield' Ventilated Filter-Cigarettes," British Journal of Addiction 77:159-65 (1982).

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hole blocking may have been a response to the visible holes of some cigarettes of that era.

Purportedly to calculate yields to the smoker under these supposedly "behavioral conditions," cigarettes were then machine smoked with a 2.4 sec puff duration, 44 sec puff interval, 47 ml puff volume ("chosen since this is the maximum obtainable from the 50 ml syringe which governs the puff volume of most commercially-available smoking machines"), and with the ventilation holes totally blocked. From this, the conclusion drawn was that smokers of low nicotine cigarettes were getting 8 to 19 fold the stated FTC yield of nicotine. But this seems about as meaningful as reporting that airplane passengers are exposed to high levels of cosmic radiation based on measurements made on the exterior of an astronaut's space suit during a space walk. In the latter context, too, the authors might well comment that "[o]ur sample was not drawn at random and our measurement techniques are open to error."

Significantly, cigarette manufacturers do not construct cigarettes with the intention that ventilation holes are to be blocked by the consumer. With today's more sophisticated manufacturing techniques, ventilation perforations are essentially invisible; and most

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consumers likely are not aware of the holes or their purpose. Moreover, because the average maximum lip position is generally understood to be less than the insertion depth into smoking machines, and considerably less than the position of the ventilation holes, hole blockage by a smoker's lips is extremely unlikely.

e. There Would Be No Practical Way To Employ Data on Actual Smoker Intake of "Tar" and Nicotine to Rate Cigarette Yields

Despite the studies confirming the relationship between FTC method yields and actual smoker "tar" and nicotine intake, some authors have criticized continued use of the FTC method and have indicated a preference for biological data. The relationship between cigarette yield and the level of biological markers in actual smokers is so complex and subject to individual variation, however, that any biologically based ratings are likely to lead only to confusing results.

While a smoker's puffing parameters can be measured in a variety of ways, there is no measure for actual intake of smoke.³³ The only way to estimate the

³³ Stephen, A., Frost, C., Thompson, S., Wald, N., "Estimating the extent of compensatory smoking," in Wald, N., Froggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 101-15 (1989) ("tar intake can only be estimated by inference from the intake of markers of other smoke components").

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"tar" and nicotine actually consumed by a particular smoker on a given day is by using measurements of biological markers derived from tests performed on that smoker.³⁴ Biological markers of smoke components in fluids (blood, plasma and urine) "giv[e] direct estimates of intake dose"; however, "[t]he individual uptake, distribution, metabolism and excretion of smoke ingredients is complex and determined by a number of different variables."³⁵

A variety of biochemical markers have been used in attempts to determine tobacco consumption. These include:

- blood nicotine
- saliva nicotine
- blood cotinine
- urine cotinine
- nicotine and cotinine metabolites in blood and urine
- blood thiocyanate

³⁴ Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology, Biochemistry & Behavior 40:139-49 (1991) ("[B]iochemical measures are absolutely necessary in order to assess the smoke exposure of the individual smoker").

See McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

³⁵ Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal of Clinical Pharmacology, Therapy and Toxicology 25(3):143-47 (1987).

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- saliva thiocyanate
- blood carboxyhemoglobin
- expired carbon monoxide

In most studies the assumption is made that the measured biochemical marker is directly related to nicotine intake. Even if such an assumption were correct, however, there would still remain a number of reasons why it would be difficult to calculate actual nicotine intake from biochemical markers.

First, some smoke related compounds are rapidly altered in the body by enzyme activity. Nicotine and carboxyhemoglobin in blood have an estimated half-life of 2-4 hours or less, whereas the half-life of cotinine is approximately 18 hours. These differences mean that different results may be obtained depending upon which markers are used and how they are used.

Second, the metabolism of nicotine is complex and involves several enzymes. Cotinine is the product of a major pathway of nicotine metabolism, but not the only one. Sensitive and selective analytical methods exist for cotinine. For these reasons, many studies have focused on cotinine in body fluids.

Third, background levels of carboxyhemoglobin and expired carbon monoxide must be subtracted from measured values to accurately measure changes in those markers.

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Whether this is done and how it is done are often not mentioned in technical reports.

In sum, each of these markers has its uses and its drawbacks, but all are subject to individual variability. The principal markers are discussed briefly below.

(i) Carbon Monoxide

Carbon monoxide is a gas phase constituent of smoke. Studies have measured CO levels by measuring carboxyhemoglobin (COHb) in blood, or alveolar CO levels in expired air.³⁶ Because carbon monoxide is not a specific marker to smoking, its use in different studies has not given reproducible results.³⁷

McMorrow *et al.* concluded that "[b]ecause a number of factors can confound attempts to demonstrate direct relations between individual smoking parameters and CO exposure, it is doubtful that CO measures can provide much useful information regarding tobacco

³⁶ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

³⁷ Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal of Clinical Pharmacology, Therapy and Toxicology 25(3):143-47 (1987).

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consumption per se."³⁸ Some of these factors include (1) CO's relatively short half-life (approximately 2 to 4 hours); (2) the variation in CO absorption and elimination rates due to physiological differences among smokers, including respiration rates, smoking history, presence of disease, and level of activity; and (3) the influence of sampling and analysis procedures.³⁹ And because carbon monoxide may be present in ambient air, occupational and environmental exposures would need to be considered before inferences could be drawn from CO levels about tobacco smoke exposure.

"CO measures should be used with caution, as they are relatively weakly related to yield . . . thus confirming that CO concentrations are highly influenced by nonsmoke related variables (physical activity, environment)." Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology Biochemistry & Behavior 40:139-49 (1991).

(ii) Thiocyanate

Thiocyanate is a metabolite of hydrogen cyanide, which has been reported to be an agent in the gas phase

³⁸ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

³⁹ Id.

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of cigarette smoke.⁴⁰ Thiocyanate levels may be determined in plasma and saliva. Because thiocyanate also is not a marker specific to smoking, different studies do not produce reproducible results.⁴¹ In addition, thiocyanate measures are influenced by other factors, such as individual differences in metabolic conversion, physiological differences, diet, and sampling and storage problems.⁴² McMorrow *et al.* therefore concluded that it is doubtful that thiocyanate can serve as an accurate, quantitative measure of tobacco consumption.⁴³

(iii) Nicotine and Cotinine

Nicotine is a fairly specific marker of tobacco smoke.⁴⁴ However, while nicotine in fluids may be an

⁴⁰ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

⁴¹ Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal of Clinical Pharmacology, Therapy and Toxicology 25(3):143-47 (1987).

⁴² *Id.*

⁴³ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

⁴⁴ See, e.g., Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal of Clinical Pharmacology, Therapy and Toxicology 25(3):143-47 (1987).

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indicator of nicotine intake from the last few cigarettes smoked, nicotine is metabolized rapidly and has a short half-life (typically 20 minutes to 2 hours).⁴⁵ Because people smoke with different frequencies and in different ways at different times of the day, the level of nicotine in the blood at any particular moment is not a useful measure of total daily intake.⁴⁶ Factors that may affect the measure of nicotine in fluids include recency of smoke exposure, time of day, and varying rates of metabolic conversion.⁴⁷

⁴⁵ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

Benowitz, N., "Dosimetric studies of compensatory cigarette smoking," in: Wald, N., Foggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 133-50 (1989).

⁴⁶ Galeazzi, R., Daenens, P., Gugger, M., "Steady-State Concentration of Cotinine as a Measure of Nicotine-Intake by Smokers," European Journal of Clinical Pharmacology 28:301-04 (1985).

McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

⁴⁷ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

For example, urinary concentrations do not correlate well with nicotine intake because of variations in urinary flow and urine pH. U.S. Department of Health and Human Services, The Health Consequences of Smoking: [Footnote continued on next page]

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The most commonly used biochemical marker for cigarette smoke intake may be cotinine, the major indirect metabolite of nicotine.⁴⁸ Cotinine is deemed more suitable to measure daily intake of cigarette nicotine.⁴⁹ Cotinine has a long half-life

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Nicotine Addiction: a report of the Surgeon General 42 (1988).

See also Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology Biochemistry & Behavior 40:139-49 (1991).

⁴⁸ Hofer, I., Nil, R., Battig, K., "Nicotine Yield as Determinant of Smoke Exposure Indicators and Puffing Behavior," Pharmacology Biochemistry & Behavior 40:139-49 (1991) ("Cotinine concentrations seem to be the best indicator for long-term smoke exposure both because of their high stability (test-retest reliability, half-life) and their relatively strong relationship with yield").

Bencowitz, N., "Dosimetric studies of compensatory cigarette smoking," in: Wald, N., Froggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 133-150 (1989) ("cotinine has become the preferred marker for intake of nicotine").

⁴⁹ "Cotinine measurements have become the most widely accepted method for assessing the intake of nicotine in long-term studies of tobacco use." U.S. Department of Health and Human Services, The Health Consequences of Smoking: Nicotine Addiction: a report of the Surgeon General 42 (1988).

"Cotinine often has been considered to be a direct measure of nicotine exposure, because the great majority of ingested nicotine is metabolized into cotinine." McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

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(approximately 18 hours),⁵⁰ and individual differences in metabolic conversion are somewhat less variable than for nicotine because cotinine levels are more stable throughout the day.⁵¹ Cotinine is less influenced by fluctuating urine pH and urine flow than nicotine,⁵² and

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Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal of Clinical Pharmacology, Therapy and Toxicology 25(3):143-47 (1987).

50 Rosa, M., Pacifici, R., Altieri, I., Pichini, S., Ottaviani, G., Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," Clinical Pharmacology Ther 52(3):324-29 (1992).

Benowitz, N., "Dosimetric studies of compensatory cigarette smoking," in: Wald, N., Froggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 133-50 (1989).

51 McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

But see Benowitz, N., "Dosimetric studies of compensatory cigarette smoking," in: Wald, N., Froggatt, P. (eds.), Nicotine, Smoking, and the Low Tar Programme 133-50 (1989) ("However, the level of cotinine does not accurately describe intake of nicotine. Individual differences in the proportion of nicotine converted to cotinine and in the rate of metabolism of cotinine per se influence the proportionality between nicotine and cotinine levels.").

52 Id.

U.S. Department of Health and Human Services, The Health Consequences of Smoking: Nicotine Addiction: a report of the Surgeon General 42 (1988).

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is somewhat less influenced by diet and environment.⁵³

While cotinine thus appears to be a somewhat more useful marker than the others, there is still little in the published cotinine studies that could reliably be employed to "adjust" FTC method data. Indeed, even if it were possible to arrive at some procedure for "adjustment," it would still be difficult to understand how biological data could be used to rate cigarettes in view of the individual variability inherent in the use of any biochemical marker. In a leading article summarizing the differences between body-level and mouth-level exposures to cigarette smoke, McMorrow and Foxx noted the importance of "individual physiological differences," a "category which has received little research attention, but contains factors that may play a major role in determining body levels of exposure such as relative metabolic conversion rates, physiological defenses, and the smoker's physical condition."⁵⁴

* * *

⁵³ Rosa, M., Pacifici, R., Altieri, I., Pichini, S., Ottaviani, G., Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake," Clinical Pharmacology Ther 52(3):324-29 (1992).

⁵⁴ McMorrow, M., Foxx, R., "Cigarette Brand Switching: Relating Assessment Strategies to the Critical Issues," Psychological Bulletin 98(1):139-59 (1985).

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Whatever the marker employed, there are flaws in the design of many of the published studies that make them entirely unsuitable for generalization. For example, many of the studies frequently cited as bearing upon compensation involved smoking behavior following periods of deprivation. Any data derived in that way are inherently suspect, for obvious reasons. A test subject deprived of food for an extended period of time will, when fed, almost inevitably eat more quickly than usual and perhaps in greater than usual quantities, even if he or she is given the very same food he or she ordinarily would eat. Similarly, one cannot simply assume that a smoker who smokes more intensively than usual following a period of deprivation is necessarily compensating for a difference in cigarette brands.

A number of studies have obvious deficiencies, reported as "small number of subjects," or of a design "subject to criticism." Many frequently cited studies are "formally incorrect from a pharmacokinetic point of view, because they have only measured plasma concentrations of markers without correcting for the individual weight, clearance rate, daily cigarette consumption and so on."⁵⁵ Repeatedly, for long term

⁵⁵ Diding, N., "Machine smoking results compared to human uptake of cigarette smoke," International Journal [Footnote continued on next page]

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studies in which smokers smoke ad libitum instead of under stressful conditions and especially after forced abstinence, the results indicate no persistence of "compensation" or "oversmoking." As discussed above, results such as those by Byrd *et al.*⁵⁶ show a direct correlation between nicotine intake by smokers and the FTC method nicotine yield of the cigarettes smoked.

Because there is no established proof that long-term compensation takes place, discussions of variation in degree of compensation as being dependent upon the yield of a smoker's cigarette are entirely hypothetical. Some studies report upward "compensation" when smokers first switch to a lower-nicotine cigarette, and others report downward "compensation" when smokers are asked to smoke cigarettes of higher nicotine yield than their customary brand. But none of these studies has been conducted for a sufficient period of time to determine the persistence of the effect when actual smokers switch from a brand with one FTC method yield to a brand with a different FTC method yield.

[Footnote continued from previous page]
of Clinical Pharmacology, Therapy and Toxicology
25(3):143-47 (1987).

56 Byrd, G., Robinson, J., Caldwell, W., deBethizy, D., "Inter-Individual Variation of Nicotine Uptake Among Smokers," Paper P127, International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II, Montreal, July 1994.

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It is therefore not possible to make any meaningful estimates of the "overall magnitude of the compensation effect." As noted above, research indicates that smokers of lower FTC method yield cigarettes do have lower blood cotinine levels than smokers of full flavor cigarettes; and there is no basis to know whether, in the abstract, such levels would be even lower absent compensation, except by inference from the fact that any compensation after brand-switching seems to be, when present, a short-term phenomenon.

CONCLUSION

We recognize that some people who favor increased governmental control over cigarette smoking tend automatically to view with skepticism any longstanding form of governmental regulation which has achieved acceptance by both elements of the tobacco industry and those fifty million Americans who choose to smoke. It would be regrettable, however, if a perception on the part of some that every aspect of smoking must be attacked were permitted to interfere with the continuation of the FTC method testing program. That program has for 25 years provided, and continues to provide, consumers with comparative information that they have found relevant to them, and which appears

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correlated to an undeniable overall reduction in the "tar" and nicotine intake of the smoking population as a whole. Any change in the system that would ignore the role played by filtration, by ventilation, and by other forms of dilution would, in our opinion, be a disservice to those who smoke.

We appreciate the interest people have in possible compensation. But there can be no real dispute that, to date, the scientific literature on compensation is limited and inconclusive. It may be that by recommending protocols for further studies, and formulating theories as to how individuals might be affected by compensation phenomena, the Conference could contribute importantly in this area. But whatever conclusions may be reached about compensation, the FTC method remains an appropriate standard for measuring cigarette properties. Smokers differ, in behavior and physiology, and no cigarette testing method could possibly reflect the variations among human beings. The reporting of FTC method yields -- by focusing not on individual characteristics, but on the properties of the cigarettes tested by a uniform, reproducible methodology -- remains a useful source of information to consumers choosing among brands.

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